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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/810,898 | 03/29/2004 | Kazuhiro Ohkouchi | 2004_0494 | 1097 |
| 513 7590 07/30/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | | |
| EXAMINER | | | | |
| VENKAT, JYOTHSNA A | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1615 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,898

Applicant(s)

OHKOUCHI ET AL.

Examiner

JYOTHSNA A. VENKAT

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 13 and 33-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 33-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 2/22/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of amendment, remarks and IDS filed on 4/29/08 and 2/22/08.

Claims 40-45 have been added as per applicants' amendment dated 4/29/08. Claims 12-13 and 33-45 are pending in the application.

In view of the amendment the 103 rejection is modified since WO 98/46215 does not teach the claimed active ingredients.

Claim Rejections - 35 USC § 112

Claim 34-36 and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

There is no support in the specification for mean particle diameter of the saccharide or sugar alcohol is between 35 to 200 microns or 43-300 microns. The support in the specification is for 30- 300 microns at page 6, 5- 90 microns or 90-500 microns at page 7 , 30-90 microns or 30-300 microns or 35-80 microns or 90-300 microns or 90-200 microns at page 8 and specific micron value for each saccharide or sugar alcohol in the examples. Applicants' have not contemplated the range claimed in claims 34-36 and 40-42.

Claim Rejections - 35 USC § 103

Claims 12-13 and 33-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of WO 98/46215 ('215) and W0 98/53798 ('798).

The instant application is claiming a quickly disintegrating solid preparation comprising:

a. an active ingredient

b. Sugar alcohol or saccharide (with a mean particle diameter of 30-300 microns

c. Disintegrating agent (carmellose calcium, carboxymethylstarch sodium, croscarmellose sodium or crosspovidone)

d. Cellulose compound (crystalline cellulose, powder cellulose, low substituted hydroxyl propyl cellulose or carmellose)

WO '215 teaches all the claimed ingredients in rapidly dissolving dosage form. See the abstract, see pages 4-5, see pages 7-9 for the active ingredients, and see page 17, lines 13-26 for claimed b. The mean particle taught by the document is within the claimed range. See paragraph bridging pages 17-18 for the various saccharide or sugar alcohols. See page 25 for wicking agent. Some of the agents are the species claimed under c as well as d. See the same page, lines 13-20 for povidone of claimed d. See examples 5, 7, and 10 teaches using both c and d in the compositions. WO '215 also discloses that the tablets are made using direct compression wherein the material were weighed and blended (page 29, line 4-5). WO '215 does not teach the active ingredients claimed in the instant application. However WO '798 teaches rapidly disintegrating tablets comprising (a) an active ingredient (2) one or more water soluble sugar alcohol such as maltitol, erythritol and xylitol at page 9, ll 1-25, low- substituted hydroxy propylcellulose at page 9, line 26 through page 10, line 16 and additives such as binders, for example hydroxy propylcellulose, crystalline cellulose and disintegrators for example crosspovidone, croscarmellose sodium, carmellose calcium at page 11, lines 3-7. Additionally WO '798 teaches the active agent can be hypertensive agents such as candersartan cilexetil at page at page 6, lines

5-6 and anti diabetic agents such as claimed voglibose and pioglitazone hydrochloride at page 6, ll 34-35 and claim 8.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare rapidly dosage preparations using all the ingredients of WO '215 document and substitute the active ingredient of WO '215 with claimed active ingredients taught by WO '798 in rapidly dissolving solid preparations. One of ordinary skill in the art would have reasonable expectation of success that the claimed dosage form with ingredients would also dissolve rapidly since using ingredient c helps in transport moisture into the dosage form, and the use of ingredient b helps in the production of a hard, non-friable, directly compressible and rapidly dissolvable in-mouth dosage form. Both WO '215 and WO '798 teach rapidly disintegrating solid preparations. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30; 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A VENKAT /
Primary Examiner, Art Unit 1615